UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

TERRY HARRIS, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. MEDTRONIC INC., MEDTRONIC USA, INC., Defendants.	**MEMORANDUM IN SUPPORT OF DEFENDANTS MEDTRONIC, INC. AND MEDTRONIC USA, INC.'S MOTION TO DISMISS** Civil No. 0:23-cv-02273 (ECT/DLM)

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INTRODUCTION

This case is an attempt by one uninjured Georgia man to turn a voluntary safety communication issued by Medtronic into a sprawling class action. The device at issue is an Implantable Cardioverter Defibrillator ("ICD") that monitors a patient's heart rhythm 24 hours a day.[1] If the ICD senses a patient's heartbeat is too slow, too fast, or irregular, it delivers pulses of electricity to the patient's heart to correct its rate. Before Medtronic could sell the ICD, the Food and Drug Administration ("FDA") scrutinized and ultimately approved the design, manufacturing specifications, and warnings under the agency's most exacting review process, known as "Premarket Approval." The FDA's Premarket Approval for the device stands to this day.

For the last five years, Plaintiff Terry Harris has had a Medtronic ICD that apparently performed without incident. Earlier this year, Medtronic notified physicians of the rare potential for certain ICDs to deliver reduced- or no-energy signals, thus failing to correct an arrhythmia. Like many other safety communications issued by medical device manufacturers, the FDA classified this safety communication as a "recall," but it did not recommend or require that the devices be removed from patients or even taken off the market. Undeterred by that reality and uninjured by his ICD, Harris asks the Court to indulge his attempt to assert a sprawling class action simply because the FDA classified

[1] The Complaint references other Medtronic cardiac devices (Complaint "Compl." ¶ 2), but the only device Plaintiff alleges he used is an ICD named Visia AF VR, model number DVAB1D1 ("the ICD" or "Harris's ICD") (*id.* ¶ 11).

Medtronic's safety communication as a "recall." That ill-conceived plan fails for a host of reasons, and Harris's Complaint should be dismissed in its entirety.

Plaintiff lacks standing to assert any claim. Harris does not allege that *his* device is defective or that *his* device failed. Instead, he asserts that "[he] would not have purchased [the ICD] had he known there was a *risk* the product *may* be defective . . . ." (Compl. ¶ 13.) But purchasers of products merely at a risk of manifesting a defect lack standing, even if other purchasers have products that manifested a defect. *Forrest v. Polaris Indus. (In re Polaris Mktg., Sales Practices & Prods. Liab. Litig.)*, 9 F.4th 793, 796 (8th Cir. 2021) ("*Polaris*"). Thus, Harris does not have standing to assert any claim.

Federal law preempts each of Harris's claims. The ICD is a Class III medical device used to monitor and regulate heart rate and rhythm. The FDA subjects such devices to its most rigorous approval process. It reviewed and approved the product along with the product's warnings. As a result, state-law claims based on the device's purported lack of safety or effectiveness, like those asserted here, are expressly preempted. 21 U.S.C. § 360k; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Bryant v. Medtronic, Inc. (In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.)*, 623 F.3d 1200, 1207 (8th Cir. 2010) ("*Sprint Fidelis*").

Harris's fraud-based claims are not alleged with particularity. The state-law consumer fraud claims, unjust enrichment, and negligent misrepresentation/omission claims all sound in fraud, yet the Complaint fails to allege *any* particulars as required by Rule 9(b). *Hammerschmidt v. GM LLC*, 583 F. Supp. 3d 1215, 1220 (D. Minn. 2022). Thus, all Plaintiff's fraud-based claims fail.

The express and implied warranty claims fail. Pre-suit notice is required before bringing a warranty claim. Harris has not alleged, and cannot allege, pre-suit notice. Harris also alleges nothing showing an actionable warranty and does not allege that his ICD has manifested a defect. *Briehl v. GMC*, 172 F.3d 623, 628 (8th Cir. 1999). For all these reasons, Harris's warranty claims fail.

Harris's product liability claims are far too vague. His manufacturing defect, design defect, and failure to warn claims include only conclusory allegations, which do not provide sufficient notice to Medtronic. *Morton v. Medtronic, Inc.*, 2015 U.S. Dist. LEXIS 187410, at *13 (D. Minn. Jan. 5, 2015). Plaintiff's failure to warn claim also ignores the Learned Intermediary doctrine. A medical device manufacturer must warn prescribing physicians, not patients, and Harris alleges only that Medtronic breached a duty to warn *him*. Thus, all Plaintiff's product liability claims fail.

BACKGROUND

A. The rigorous Premarket Approval process

Prescription-only Class III devices—like the ICD—are subject to "the FDA's strictest regulation," namely "[P]remarket [A]pproval" ("PMA"). *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001). As a Class III device, the ICD is "use[d] in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or to address conditions that "present[] a potential unreasonable risk of illness or injury." *Riegel*, 552 U.S. at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

PMA "is a 'rigorous' process." *Riegel*, 552 U.S. at 317. Manufacturers submit detailed information about the design, manufacture, and labeling of their devices, which the FDA then scrutinizes, spending an average of 1,200 hours on each submission. *Id.* at 317-18. The FDA is required to "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). After conducting this thorough cost-benefit analysis, the FDA may "grant[] [PMA] only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (quoting 21 U.S.C. § 360e(d)). If the FDA is not satisfied with the PMA application, it can require revisions. *Id.* at 318-19 (citing 21 U.S.C. § 360e (c)(1)(G) & 21 C.F.R. § 814.44(e)).

The FDA's rigorous oversight continues after approval. After PMA, the manufacturer may not "make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing § 360e(d)(6)(A)(i)); *accord* 21 C.F.R. § 814.80. To make such changes, a manufacturer must submit a supplemental application for FDA approval, which is evaluated with the same rigor as an original application. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)).

Through the PMA process, the FDA has final and exclusive enforcement authority with respect to the requirements imposed on Class III devices. The FDA can prohibit sale, withdraw approval, or mandate additional warnings. *See* 21 U.S.C. § 352 (labeling changes); § 360h(a) (notification requirements); § 360h(e)(1) (recalls). Private citizens cannot second guess the FDA's judgments. The Food, Drug, and Cosmetic Act ("FDCA")

does not include a private right of action, thus leaving "no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 & n.4 (citing 21 U.S.C. § 337(a)).

B. Harris's ICD received FDA Premarket Approval

Harris's ICD is a Class III medical device approved through the FDA's exacting PMA process described above. (*See* Declaration of Richard Tabura, "Tabura Decl.", Exs. A-B.)[2] The ICD is part of a family of Medtronic ICDs that received initial approval on October 9, 1998, under PMA No. P980016. (*Id.*) Since then, the FDA has approved several supplemental PMA applications for this family of ICDs, covering changes to the devices or their labeling. Harris's ICD received FDA approval on January 19, 2016 through PMA No. P980016, Supplement No. S551. (Tabura Decl., Ex. B.). Medtronic cardiac devices

[2] Under Federal Rule of Evidence 201, the Court can and should take judicial notice of the FDA's supplemental premarket approval listing and approval order for Harris's ICD, located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&applicant=&tradename=&productcode=&pmanumber=p980016&supplementnumber=&advisorycommittee=&docketnumber=&supplementtype=&expeditedreview=&center=&ivdproducts=off&combinationproducts=off&decisiondatefrom=&decisiondateto=09%2F21%2F2023&noticedatefrom=&noticedateto=&znumber=&pagenum=500 and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980016S551. Courts in this circuit routinely take judicial notice of FDA premarket and supplemental approvals. *E.g.*, *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 984 (E.D. Mo. 2014) (judicially noticing FDA premarket approval listings); *Redd v. DePuy Orthopaedics, Inc.*, 48 F. Supp. 3d 1261, 1266 (E.D. Mo. 2014) (same). For the Court's convenience, printouts of these public FDA records are attached to the concurrently filed Declaration of Richard Tabura "Tabura Decl." as Exhibits A-B.

like the ICD have sustained and extended patients' lives for over 25 years. (Tabura Decl., Ex. A) (FDA's PMA listing for Harris's ICD).

C. Harris's allegations

Harris is a resident of Union City, Georgia. (Compl. ¶ 10.) He alleges that, on June 20, 2018, Patrick Egbe, M.D. implanted a Medtronic ICD at South Fulton Medical Center in Fulton County, Georgia. (*Id.* ¶ 11.) Beyond that, the Complaint says almost nothing about Harris. It does not identify his medical condition or what product materials he or his physician reviewed before selecting and implanting his Medtronic ICD. Nor does the Complaint allege that Harris's ICD has malfunctioned. Harris merely professes, without supporting facts, that he "suffered personal injury" (*id.* ¶ 14) and that he "sustained and will continue to sustain lasting pain and suffering" (*id.* ¶ 71).

On May 10, 2023, Medtronic sent to physicians a voluntary safety communication, sometimes referred to as a "Dear Doctor" letter, informing them of a rare potential for reduced-energy therapy in its ICDs and certain related devices that contain a design feature called a "glassed feedthrough." (Compl. ¶ 22, n.12; Tabura Decl., Ex. C[3].) As of April 10, 2023, Medtronic was aware of just 27 out of around 816,000 devices worldwide (0.003%) that had experienced the "low-energy" malfunction, which theoretically could cause a device to fail to correct an arrhythmia. (*Id.*) None of the reported malfunctions resulted in death. (*Id.*) In the May 10, 2023 letter, Medtronic also informed physicians that

[3] For ease of reference, true and correct copies of the articles cited in Harris's Complaint with relevant portions highlighted are attached to the concurrently filed Declaration of Richard Tabura as Exhibits C-F.

prophylactic device replacement was not recommended, and it provided device reprogramming recommendations that the physician could perform to further minimize the already low malfunction risk. (*Id*.)

In June 2023, the FDA classified Medtronic's May 10, 2023 letter as a Class I recall. (Compl. n.18; Tabura Decl., Exs. D-E). The FDA reiterated the "rare potential" for reduced- or no-energy output when the ICD attempted to deliver a charge. (*Id.*) And it echoed Medtronic's message to physicians that "[p]rophylactic device replacement is NOT recommended" and provided reprogramming recommendations. (*Id.*) The FDA did not order removal of the ICD from the market or revoke its PMA for the devices, and it continues to permit physicians to implant them. (*Id.*)[4]

Based on these allegations, Harris asserts nine claims: two statutory counts for alleged violations of the Minnesota False Statements in Advertising Act ("MFSAA") and the Minnesota Deceptive Trade Practice Act ("MDTPA"), and seven common-law counts for unjust enrichment, negligent misrepresentation/omission, breach of express warranty, breach of implied warranty, strict product liability – manufacturing defect, negligent design defect, and negligent failure to warn. (Compl. ¶¶ 50, 66, 80, 90, 101, 116, 120, 130, 135.)

LEGAL STANDARD

"In reviewing a motion to dismiss for failure to state a claim under Rule 12(b)(6), a court must accept as true all of the factual allegations in the complaint and draw all

[4] Harris also references two other recalls involving Medtronic cardiac devices. (Compl. ¶¶ 17, 25.) Those recalls, however, involved different models and different potential malfunctions. (*Id.*, Ex. A, n.15; Tabura Decl., Ex. F) (recalls referencing different products).

reasonable inferences in the plaintiff's favor." *Hernandez-Diaz v. Experian Info. Sols., Inc.*, 2023 U.S. Dist. LEXIS 88622, at *5 (D. Minn. May 22, 2023) (internal citation and quotations omitted) (Tostrud, J.). "The complaint must state a claim to relief that is plausible on its face." *Id.* (quotations omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Iqbal*, 556 U.S. at 678). When a defendant challenges subject matter jurisdiction—including standing—under Rule 12(b)(1), "a court reviews the pleadings alone, and the non-moving party receives the same protections as it would defending against a motion brought pursuant to Rule 12(b)(6)." *Carlsen v. GameStop, Inc.*, 112 F. Supp. 3d 855, 860 (D. Minn. 2015).

ARGUMENT

I. Lack of standing and federal preemption bar all of Harris's claims.

All Harris's claims fail for two core reasons under established Eighth Circuit precedent. First, his claims fail because his ICD has not manifested a defect, which means he lacks standing to assert any claim. Second, Harris's claims attempt to second-guess the FDA's determination that his ICD is safe and effective, which means they are preempted under the FDCA.

A. All Harris's claims fail because he alleges no injury-in-fact.

Harris must show "he has suffered an injury in fact—an invasion of a legally protected interest that is both concrete and particularized and actual or imminent, not conjectural or hypothetical." *Polaris*, 9 F.4th at 796 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)) (internal quotations omitted). To avoid dismissal, Harris "must

allege sufficient facts to support a reasonable inference that [he] can satisfy the elements of standing." *Missouri v. Biden*, 52 F.4th 362, 368 (8th Cir. 2022). The Eighth Circuit recently reaffirmed that purchasers of products that are merely at risk of manifesting a defect lack standing to assert the claims Harris pursues here. *Polaris*, 9 F.4th at 797 ("The purchasers have alleged nothing more than the existence of a defect in a product line or ownership of a product that is at risk for manifesting a defect.").

Polaris was a putative class action involving off-road vehicle engines with an alleged design defect that purportedly caused hot air to build up inside the engine and rendered them "vulnerable to catastrophic fires." 9 F.4th at 795. The engines were subject to a recall. *Id.* The *Polaris* plaintiffs, however, did not allege that *their* engines were defective or had caught fire, or that they had stopped using their vehicles as a result of the recall. *Id.* They still asserted claims for breach of warranty, fraudulent omission, and violations of various consumer protection laws. *Id.* To support standing, plaintiffs claimed—as Harris does—that they had suffered economic damages because "they would not have purchased the vehicles at all or would have paid significantly less if they had known of the alleged defect." *Id.* The Eighth Circuit affirmed the district court's dismissal for lack of standing because plaintiffs had not alleged facts "as to how the defect manifests in their respective vehicles, and therefore failed to allege a particularized and actual injury." *Id.* at 796-97.

The *Polaris* court likened the plaintiffs' claims to *O'Neil v. Simplicity, Inc.*, 574 F.3d 501 (8th Cir. 2009), a putative class action asserting express warranty, implied warranty, unjust enrichment, and Minnesota consumer protection claims over a recalled

crib that contained a potential manufacturing defect. *Polaris*, 9 F.4th at 796. As in *Polaris*, the *O'Neil* Court held plaintiffs had no injury-in-fact because ***their*** cribs had not manifested the alleged defect. *Id.* (citing *O'Neil*, 574 F.3d at 504-05).

Like *Polaris* and *O'Neil*, Harris's claims are based on a *potential* defect in his ICD. He tries to show injury by alleging that "[he] would not have purchased Defendants' medical device had he known there was a ***risk*** the product ***may*** be defective . . . ." (Compl. ¶ 13) (emphasis added). But because Harris has not alleged *his* ICD manifested a defect, he has no injury-in-fact. *Polaris*, 9 F.4th at 988 ("In this circuit, plaintiffs claiming economic injury do not have Article III standing in product defect cases unless they show a manifest defect."); *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir. 2014) ("Without any particularized reason to think the consumers' own packages of Hebrew National beef actually exhibited the alleged non-kosher defect, the consumers lack Article III standing"); *George v. Uponor Corp.*, 988 F. Supp. 2d 1056, 1070 (D. Minn. 2013) ("Plaintiffs have not plausibly alleged suffering any actual manifestation of the defect, meaning they lack standing to pursue not only their warranty claims but all other claims in this action.").

Nor has Harris adequately alleged injury-in-fact based on his vague allegations of personal injury (Compl. ¶ 14) and pain and suffering (*id.* ¶ 71). There are no facts or other references in the Complaint to Harris suffering any physical harm because of his ICD. Had any such harm occurred, no doubt it would have been the headline of Harris's Complaint. On a motion to dismiss, the Court accepts the *factual* allegations, but it "do[es] not accept as true any 'legal conclusion couched as a factual allegation.'" *Brown v. Green Tree*

Servicing, LLC, 820 F.3d 371, 372 (8th Cir. 2016) (quoting *Iqbal*, 556 U.S. at 678). The bare assertion that Harris has a personal injury—unsupported by any facts—is a legal conclusion the Court should not accept, particularly given Harris's express allegation that there was only "a *risk* the product *may* be defective . . . ." (Compl. ¶ 13) (emphasis added). *See Lopez v. Minn. Vikings Football Stadium, LLC*, 2018 U.S. Dist. LEXIS 98371, at *11 (D. Minn. June 12, 2018) (dismissing negligence-based personal injury claim because allegations were "conclusory").

B. All Harris's claims are preempted by federal law.

Harris's claims also fail because the FDA has determined that his ICD is safe and effective. And despite the FDA classifying Medtronic's safety communication as a "recall," it has not revoked PMA or required Medtronic to stop making the device or withdraw it from the marketplace. The FDA's continued approval preempts every claim Harris asserts.

1. Harris's claims are expressly preempted under FDCA section 360k(a).

Congress determined that the FDA, not juries applying the divergent laws of fifty States, should determine whether a particular medical device is safe and effective. *See Riegel*, 552 U.S. at 326; *see also* H.R. Rep. No. 94-853 at 12 (1976). Therefore, section 360k(a) of the Medical Device Amendments to the FDCA broadly preempts state statutory and common-law claims that "relat[e] to the safety or effectiveness" of a PMA-approved device and would impose "any requirement which is different from, or in addition to," those imposed by the federal government. 21 U.S.C. § 360k(a); *see Riegel*, 552 U.S. at 321-26.

In *Riegel*, the Supreme Court established a two-step process to determine whether a claim is expressly preempted by the FDCA. *See* 552 U.S. at 321-22. First, the court must "determine whether the Federal Government has established requirements applicable to" the medical device. *Id.* at 321. Second, the court must decide whether the plaintiff's claim is "based upon [state law] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* at 322 (citing 21 U.S.C. § 360k(a)). A claim is expressly preempted when these two conditions are met. Harris's claims easily satisfy the *Riegel* test and thus are preempted.

(a) Step one: The ICD is Premarket Approved.

The first step is readily satisfied because Harris's ICD is a Class III device approved through the FDA's PMA process. (*See* Tabura Decl., Ex. B.) In *Riegel*, the Supreme Court held that "[PMA] . . . imposes [federal] 'requirements,'" as the term is used in section 360k(a). 552 U.S. at 322.

(b) Step two: Harris's claims are based on purported state law requirements that are "different from, or additional to," federal law.

Riegel's second step also is satisfied. Whether couched as consumer fraud, breach of warranty, or product liability, Harris's claims would impose state-law "requirements" covered by section 360(k)(a)'s express preemption clause. 552 U.S. at 324-25.

Tort and contract liability are just as much state-law "requirement[s]" as formal state regulations. In *Sprint Fidelis*, the Eighth Circuit affirmed dismissal of state common law failure to warn, design defect, manufacturing defect, express warranty, and fraud claims based on *Riegel*'s preemption principles. 623 F.3d at 1203. The claims asserted in *Sprint*

Fidelis boiled down to a plaintiff's assertion that a Class III PMA-approved device was defective and unsafe and that the manufacturer "failed to adequately warn of known defects," in part because the device was the subject of a Class I recall. *Id.* at 1205-08.

Like *Sprint Fidelis*, Harris's consumer protection, unjust enrichment, negligent misrepresentation/omission, warranty, and product liability claims are all based on assertions that his ICD is unsafe and ineffective, and each claim would impose different or additional requirements than those imposed by the ICD's PMA. (Compl. ¶¶ 45, 50, 67, 69, 92, 93, 97, 99, 101, 102, 114, 116, 120, 125, 126.) Stated differently, Harris simply disagrees with the FDA that his ICD is safe and effective. Another court in this district facing similar allegations regarding a Medtronic ICD in a putative class action aptly explained the problem with claims like Harris's:

> [Plaintiff] would have to persuade a jury that the devices were not "safe," "sound," "reliable," "effective," "non-defective," and "fit and proper for their intended use" – which is no different than persuading a jury that the devices are not "safe and effective." These claims are therefore preempted under *Sprint Fidelis*.

Kinetic Co. v. Medtronic, Inc., 2011 U.S. Dist. LEXIS 42398, at *11-13 (D. Minn. Apr. 19, 2011). The same is true for Harris: his claims uniformly hinge on convincing a jury that his ICD is not safe and effective, and thus would require the Court or jury to impose state standards different than those under the FDCA. Put another way, Harris's claims "are a frontal assault on the FDA's decision to approve a PMA Supplement after weighing the product's benefits against its inherent risks," *Sprint Fidelis*, 623 F.3d at 1207, and are thus preempted under *Riegel* and *Sprint Fidelis*. This Court had no trouble rejecting similar claims in the past and should do so again here. *Marshall v. Smith & Nephew, Inc.*, 2020

U.S. Dist. LEXIS 10581, at *17 (D. Minn. Jan. 22, 2020) (preempting product liability and misrepresentation claims related to PMA-approved device); *Reed v. St. Jude Med.*, 2018 U.S. Dist. LEXIS 152042, at *9 (D. Minn. July 24, 2018) (preempting warranty, false advertising, and product liability claims asserted against a PMA-approved device).

2. Harris also does not allege a non-preempted "parallel claim."

In one extremely narrow situation, a claim involving a PMA-approved device can evade preemption under the limited "parallel claim" exception if it neither (a) imposes requirements different from the PMA requirements (which would be expressly preempted), nor (b) attempts to step into FDA's shoes to enforce the FDCA (which would be impliedly preempted). *Sprint Fidelis*, 623 F.3d at 1204; *Riegel*, 552 U.S. at 321-22. Under "implied preemption," the FDA has the sole authority to investigate violations of the FDCA, its amendments, and its regulations, and "has at its disposal a variety of enforcement options that allow it to make a measured response" to wrongdoing it uncovers. *Buckman*, 531 U.S. at 349. Within this narrow gap between *Riegel*'s express preemption and *Buckman*'s implied preemption sits a theoretical "parallel claim." *Sprint Fidelis*, 623 F.3d at 1204.

Harris fails to allege a parallel claim that threads this narrow gap. Nowhere does he allege that Medtronic failed to include FDA-approved warnings. *See Sprint Fidelis*, 623 F.3d at 1205. Nowhere does he allege that his ICD did not follow Medtronic's FDA-approved design or FDA-approved manufacturing requirements. *See id.* at 1206-07. Although he cursorily alleges Medtronic "fail[ed] to adhere to current good manufacturing practices" (Compl. ¶ 13), this exact allegation was found insufficient by the Eighth Circuit in *Sprint Fidelis*, 623 F.3d at 1206-07; *accord Reed*, 2018 U.S. Dist. LEXIS 152042, at *9;

Morton v. Medtronic, Inc., 2015 U.S. Dist. LEXIS 187410, at *12-13 (D. Minn. Jan. 5, 2015). He superficially asserts that Medtronic "fail[ed] to disclose adverse events associated with the use of the [ICD]" (Compl. ¶ 68), but that allegation too has been found to "simply be an attempt by private parties to enforce the [Medical Device Amendments], claims foreclosed by § 337(a) as construed in *Buckman*," *Sprint Fidelis*, 623 F.3d at 1205-06 (holding allegation that Medtronic failed to timely file adverse event reports was impliedly preempted and not a "parallel claim"). The "parallel claim" exception is inapplicable and does not save Harris's claims from dismissal.

II. Harris's claims fail for several independent reasons beyond standing and preemption.

Even if Harris could establish standing and evade federal preemption (he cannot), each of his claims fails for independent reasons.

A. Harris's fraud-based claims (Counts 1-4) fail for at least four independent reasons.

At the heart of Harris's MFSAA, MDTPA, unjust enrichment, and negligent misrepresentation/omission claims is his groundless allegation that Medtronic misled him about his ICD being safe and effective. (*See, e.g.*, Compl. ¶¶ 45, 46, 50, 55, 67, 68, 69, 80, 90, 92, 93.) These claims fail for four independent reasons. *First*, whether based on misrepresentations or omissions, Harris fails to allege particularized facts as required by Rule 9(b). *Second*, under an omissions theory, his fraud-based claim fails because he has not alleged Medtronic had presale knowledge of a defect that it could have disclosed. An omission theory also cannot support a MFSAA claim as a matter of law. *Third*, Harris does

not allege he viewed any false statement in Minnesota, which bars his MFSAA claim. *Fourth*, he does not allege irreparable injury or a threat of future harm, so he cannot pursue the only remedy available for this MDTPA claim, injunctive relief.

1. Harris fails to allege his fraud-based claims with particularity.

Rule 9(b) "requires 'particularity' when pleading 'fraud or mistake.'" *Hammerschmidt*, 583 F. Supp. 3d at 1220; *Chin v. Gen. Mills, Inc.*, 2013 U.S. Dist. LEXIS 77345, at *20-21 (D. Minn. May 31, 2013) ("The heightened pleading standard in Rule 9(b) applies to claims of unjust enrichment [], claims of fraudulent misrepresentation [], and claims under Minnesota's . . . consumer protection statutes []."). "To satisfy Rule 9(b), the complaint must plead the who, what, where, when, and how of the alleged fraud." *Hammerschmidt*, 583 F. Supp. 3d at 1220.

Harris fails to meet this particularity requirement for any of his fraud-based claims. The only details he provides are his name, where he resides, the ICD model he bought, and where it was implanted. (Compl. ¶¶ 10-11.) But these allegations have nothing to do with any alleged fraud. He alleges no particulars about what he viewed and relied on before having his ICD implanted, including where, when, or how he viewed the unidentified material from Medtronic that supposedly misled him. Nor does he allege any particularized facts showing what was false about any material he saw. All he alleges is that Medtronic "misrepresent[ed] that the Devices were safe and not defective when in fact these products are unsafe because they were not operating properly." (*Id.* ¶ 50). But generic, "[c]onclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy [Rule 9(b)]." *Hammerschmidt*, 583 F. Supp. 3d at 1220. Harris alleges no

particulars, and thus all his fraud-based claims should be dismissed. *See Luckey v. Alside, Inc.*, 245 F. Supp. 3d 1080, 1098 (D. Minn. 2017) ("Because there are no factual allegations about who heard or saw and relied on Alside's sales statements and when, it is not clear how the existence of the alleged misrepresentations caused Plaintiffs' damages.").

2. Any omissions-based theory fails because Harris does not allege presale knowledge of an actual defect.

Harris's MFSAA, MDTPA, unjust enrichment, and negligent misrepresentation/omission claims include an omission theory suggesting that Medtronic failed to disclose that his ICD was defective. (*See, e.g.*, Compl. ¶¶ 47, 50, 68, 80, 93.) Any omissions theory fails for two reasons.

First, "[a] showing of presale knowledge of an alleged defect is required to state a claim for fraudulent omission." *Hammerschmidt*, 583 F. Supp. 3d at 1222. But nowhere does Harris allege facts showing that Medtronic knew of the ICD's potential for reduced-energy or no-energy therapy at the time his ICD was implanted on June 20, 2018. Harris cites an irrelevant March 2018 recall related to *other* cardiac devices that did not include his model of ICD and involved a different potential malfunction (Compl. ¶¶ 17, 25, 28, Ex. A (2018 recall)), but allegations about other defects in other devices do not show presale knowledge of the potential defect Harris alleges. *Hammerschmidt*, 583 F. Supp. 3d at 1222 ("[W]hile the TSB might suggest that GM was on notice of the potential for some PPS pads to tear, the allegations do not support the inference that GM had knowledge of a risk that the airbags might not deploy."). Thus, to the extent the MFSAA, MDTPA and common-law fraud claims are based on an omissions theory, they fail as a matter of law. *See id*, 583

at 1223 ("Put simply, Plaintiffs have failed to sufficiently allege that . . . GM had presale knowledge of any safety implications related to the [defect]."); *see also Knotts v. Nissan N. Am., Inc.*, 346 F. Supp. 3d 1310, 1325 (D. Minn. 2018) ("Knotts offers only a conclusory allegation that NNA knew of the alleged CVT defect prior to bringing the subject vehicles to market").

Second, any omissions-based MFSAA claim fails for the additional reason that the MFSAA only provides a claim for false or deceptive representations, not omissions. Minn. Stat. ¶ 325F.67; *Johannessohn v. Polaris Indus.*, 2017 U.S. Dist. LEXIS 99843, at *10 (D. Minn. June 27, 2017) ("The plain language of the [MFSAA] requires proof of an untrue, deceptive, or misleading statement in an advertisement."). Harris ignores this requirement and asserts an omissions theory. (Compl. ¶¶ 47, 50.)

3. Harris did not view any alleged false statement in Minnesota, so his MFSAA claim (Count 1) fails.

"To plead a MFSAA claim, a party must allege, among other elements, that the defendant's false statements occurred in Minnesota." *Gisairo v. Lenovo (U.S.) Inc.*, 516 F. Supp. 3d 880, 891 (D. Minn. 2021). Harris makes no allegations to satisfy this central requirement. *See Knotts v. Nissan N. Am., Inc.*, 346 F. Supp. 3d 1310, 1327 (D. Minn. 2018) ("Because the Complaint fails to allege that the false statement occurred in Minnesota, the claim fails for this additional reason."). Harris resides in Georgia, and his ICD was implanted in Georgia. (Compl. ¶¶ 10-11.) Nowhere does Harris allege he viewed any false statement in Minnesota. And even when a Minnesota company's representations are at issue, they are not actionable if the plaintiff received them out of state. *See, e.g.*,

McAteer v. Target Corp., 2018 U.S. Dist. LEXIS 124923, at *7 n.2 (D. Minn. July 26, 2018).

4. Harris fails to allege irreparable future injury, so his MDTPA claim (Count 2) fails.

The only remedy available under the MDTPA is injunctive relief. Minn. Stat. § 325D.45; *Nelson v. Am. Fam. Mut. Ins. Co.*, 262 F. Supp. 3d 835, 862 (D. Minn. 2017), *aff'd*, 899 F.3d 475 (8th Cir. 2018). To state a basis for injunctive relief under the MDTPA, "a plaintiff must allege a threat of future harm to himself." *Johnson v. Bobcat Co.*, 175 F. Supp. 3d 1130, 1140 (D. Minn. 2016).

In *Johnson*, plaintiff asserted Minnesota consumer protection claims related to his purchase of an alleged defective tractor. 175 F. Supp. 3d at 1135. For the MDTPA claim, plaintiff sought an injunction to prevent defendant from falsely advertising the qualities of the tractor. *Id.* at 1141. The plaintiff, however, did not assert that he intended to buy another tractor, and his claims were based on past damage. *Id.* The court explained, "now that [plaintiff] knows about the alleged defects in the [tractor], it is unlikely that he will be deceived again." *Id.* The court dismissed the MDTPA claim, holding "[plaintiff's] claims for injunctive relief fail for the simple reason that he does not make any allegations regarding irreparable injury or threat of future harm." *Id.*

The same is true here. The MDTPA provides injunctive relief for deceptive trade practices, but Harris cannot be deceived in the future. Harris seeks to enjoin Medtronic from selling the ICD (Prayer ¶ B), but like *Johnson*, nowhere does he allege he has any intention to buy another ICD. He seeks an order enjoining Medtronic from "suggesting or

implying" his ICD is safe and effective (*id.* ¶ C), but he already thinks his ICD is unsafe, so he cannot be deceived. He also seeks an order requiring Medtronic to engage in a "corrective advertising campaign" (*id.* ¶ D), but he already acknowledged that Medtronic has sent physicians a Dear Doctor letter describing the rare issue and the FDA has already classified the letter as a Class I recall. (Compl. n.18.)

At best, Harris has alleged a rare possibility of malfunction in his ICD. This has nothing to do with deceptive trade practices, and these allegations fail to allege "nonspeculative future harm as to himself," so his MDTPA claim fails. *Gisairo*, 516 F. Supp. 3d at 891 ("To withstand a motion to dismiss, a plaintiff asserting a claim under the MDTPA must allege an irreparable injury or threat of future harm ***to the plaintiff***.") (emphasis added).

B. Harris's warranty claims (Counts 5-6) fail for three additional reasons.

Harris tries to allege a breach of an unidentified express warranty and of the implied warranty of merchantability. But these claims fail as a matter of law for three reasons. First, Harris has not alleged pre-suit notice. Second, his vague allegations about purported assertions by Medtronic about his ICD's safety do not show an actionable warranty. Third, his implied warranty claims fail because he has not alleged facts showing his ICD manifested any defect or was unmerchantable.

1. Harris does not and cannot allege pre-suit notice of his warranty claims (Counts 5-6), nor can he.

Under Minnesota law[5], a plaintiff must provide a defendant with pre-suit notice of warranty claims. Minn. Stat. § 336.2-607(3)(a) ("the buyer must within a reasonable time after the buyer discovered or should have discovered any breach notify the seller of breach or be barred from any remedy"). Harris gave no such notice, and he does not allege otherwise. His express and implied warranty claims fail for this reason alone. *See Wheeler v. Subaru of Am., Inc.*, 451 F. Supp. 3d 1034, 1038-39 (D. Minn. 2020) ("Because the Complaint fails to allege notice to that effect, [plaintiff's] claim for breach of warranty must be dismissed."); *Hammerschmidt*, 583 F. Supp. 3d at 1223 (dismissing implied warranty claims for failure to provide pre-suit notice).

2. Harris fails to allege an actionable express warranty (Count 5).

An express warranty claim requires facts showing: (1) the existence of a warranty; (2) breach; and (3) a causal link between the breach and the alleged harm. *Knotts*, 346 F. Supp. 3d at 1320. But to be actionable, the alleged warranty statement must be specific and measurable. *Podpeskar v. Makita U.S.A. Inc.*, 247 F. Supp. 3d 1001, 1009 (D. Minn. 2017). "[A]dvertisements that have been found to constitute express warranties contain very

[5] Harris fails to allege which state law applies to his common law claims, which is itself grounds for dismissal. *In re Samsung Galaxy Smartphone Mktg. & Sales Practices Litig.*, 2018 U.S. Dist. LEXIS 54850, at *13 (N.D. Cal. Mar. 30, 2018) ("Due to variances among state laws, failure to allege which state law governs a common law claim is grounds for dismissal."). In any event, the Court should default to Minnesota law even though Harris is a Georgia resident. *Bbserco, Inc. v. Metrix Co.*, 324 F.3d 955, 960 n.3 (8th Cir. 2003) ("[W]hen neither party raises a conflict of law issue in a diversity case, the federal court simply applies the law of the state in which the federal court sits.").

specific claims and promises as to how a certain product will perform." *Masepohl v. Am. Tobacco Co.*, 974 F. Supp. 1245, 1253 (D. Minn. 1997).

Harris, on the other hand, alleges only that Medtronic "warranted that the Devices were safe and fit for the purposes intended, that they were of merchantable quality, and that they did not pose dangerous health risks." (Compl. ¶ 97.) He also claims a "description for the Devices"—which he does not identify—"represents that the use of these medical devices serves to monitor and protect the individual from a life-threatening cardiac event." (*Id.* ¶ 98.) But these statements are not the type of specific promises that constitute an actionable warranty. *See Anderson v. 1399557 Ont. Ltd.*, 2019 U.S. Dist. LEXIS 190608, at *23 (D. Minn. Nov. 4, 2019) ("These are general statements about the quality of the goods—statements that are not measurable, verifiable, or refutable."). Like *Anderson*, Harris's allegations that Medtronic warranted that his ICD was "safe and fit for the purposes intended," "merchantable," and "serve[s] to monitor and protect the individual from a life-threatening cardiac event" are generic statements about the product. They are not measurable, verifiable, or refutable. Thus, the purported warranty statements are not actionable. *See Podpeskar*, 247 F. Supp. 3d at 1009 ("[C]ourts typically do not construe general statements about the quality of a product or service as express warranties.").

3. Harris's implied warranty claim (Count 6) also fails because he does not allege facts showing a defect or unmerchantability.

To state an implied warranty claim, Harris must show his ICD is so defective as to be unmerchantable. *See Peterson v. Bendix Home Sys., Inc.*, 318 N.W.2d 50, 52-53 (Minn. 1982) ("[The implied warranty of merchantability] is breached when the product is

defective to a normal buyer making ordinary use of the product."). But Harris does not even allege that his ICD manifested a defect. He does not claim that it malfunctioned or injured him or that he required revision surgery. Instead, he alleges only that his ICD has a "risk" that it "may be defective" (Compl. ¶ 13). These allegations do not state an implied warranty claim. *Briehl*, 172 F.3d at 628 (affirming dismissal of implied warranty claim "[s]ince the Plaintiffs have failed to allege any manifest defect and their vehicles perform in a satisfactory manner."); *Browe v. Evenflo Co.*, 2015 U.S. Dist. LEXIS 82540, at *6 (D. Minn. June 25, 2015) ("Having failed to allege that she suffered an injury causally related to the alleged defect, Browe's claim arising from the implied warranty of merchantability fails as a matter of law.").

C. Harris's product liability claims (Counts 7-9) fail for additional reasons.

Despite not suffering physical injury, Harris seeks to allege traditional product liability theories. But under any such theory, he has not alleged facts showing a defect or causation. And contrary to the Learned Intermediary Doctrine, Harris does not allege Medtronic failed to warn his physician or that any failure affected his physician's prescribing decision. His product liability claims thus fail.

1. The product liability claims are all insufficiently plead.

Courts in this district have dismissed generic product liability claims that—like Harris's—do no more than state, in conclusory fashion, that a product was defective and caused injury. *Dolan v. Bos. Sci. Corp.*, 2021 U.S. Dist. LEXIS 34374, at *6 (D. Minn. Feb. 23, 2021) ("What the Complaint lacks is factual allegations specific to [plaintiff] and her alleged injuries."); *Morton v. Medtronic, Inc.*, 2015 U.S. Dist. LEXIS 187410, at *13

(D. Minn. Jan. 5, 2015) ("Plaintiff's allegations do not provide sufficient notice of the basis of his claims against Medtronic because he has failed to identify any manufacturing defect that would form the basis of his . . . claims.").

In *Dolan*, plaintiff asserted design defect and failure to warn claims related to an implanted medical device. 2021 U.S. Dist. LEXIS 34374, at *2. But the design defect theory did nothing but state that the defendant's "design defects caused [plaintiff's] injuries." *Id.* at *4. And the failure to warn theory did not allege how any failure to warn caused plaintiff's injuries. *Id.* at *7. Despite the complaint including extensive allegations about the nature of the alleged defects, it had a "dearth" of allegations specific to the plaintiff. *Id.* at *6. And thus the court dismissed the product liability claims. *Id.* at *9.

Harris's product liability claims are worse. His manufacturing defect claim states that his ICD "differed from [Medtronic's] intended result" (Compl. ¶ 120) but does not explain what differed or how the alleged divergence resulted from manufacturing errors. He claims his ICD was defective in design but provides no factual detail other than to say the device causes improper energy outputs (*id.* ¶ 125), without identifying a superior alternative. He claims Medtronic breached a duty to warn (*id.* ¶¶ 133-136) but does not allege any specific warning that should have been provided. Thus, Harris's product liability claims fail for not adequately alleging a defect. *Adams v. Stryker Pain Pump Corp.*, 2010 U.S. Dist. LEXIS 127040, at *5 (D. Minn. Dec. 1, 2010) ("This threadbare allegation does not plead facts showing that the pain pump was unreasonably dangerous . . . [n]or does this allegation note any particular manufacturing defect or deviation").

2. The Learned Intermediary Doctrine bars Harris's failure to warn claim (Count 9).

A prima facie failure to warn claim requires establishing a duty to warn, breach, and causation. *See Dolan*, 2021 U.S. Dist. LEXIS 34374, at *6. And under the Learned Intermediary Doctrine, "a warning about a medical device need only be given to a prescribing physician." *Id.* at *6-7. This doctrine forecloses Harris's failure to warn claims for two reasons.

First, Harris only alleges that Medtronic failed to warn *him* and "class members" (Compl. ¶ 133); nowhere does he claim Medtronic failed to warn a prescribing physician, let alone his. *Mozes v. Medtronic, Inc.*, 14 F. Supp. 2d 1124, 1130 (D. Minn. 1998) ("The Court finds that Medtronic had a duty to warn only the surgeon who implanted the [medical device] into [plaintiff] of the dangers associated with it.").

Second, Harris must also show that any alleged failure to warn would have changed his doctor's prescribing decision (i.e. causation). Yet his Complaint lacks such allegations. *Dolan*, 2021 U.S. Dist. LEXIS 34374 at *7 (dismissing failure to warn claim because the plaintiff did not allege how the device manufacturer's failure to warn the prescribing physician caused plaintiff's injuries); *Marshall v. Smith & Nephew, Inc.*, 2020 U.S. Dist. LEXIS 10581, at *21 (D. Minn. Jan. 22, 2020) (dismissing failure to warn claim in part because plaintiff failed to allege "how such a hypothetical warning would have changed the course of events.").

CONCLUSION

Harris's Complaint exemplifies why the Eighth Circuit has been vigilant in the areas of standing and preemption for Class III medical devices. If his allegations were enough to state a claim, an uninjured patient with a perfectly working device could turn any Dear Doctor letter or recall by a medical device manufacturer into a nationwide class action by shoehorning it into a variety of ill-fitting causes of action. A plaintiff could simply state the product was "not safe" because of a recall, undermining the regulatory scheme put in place by Congress to support the development of life-saving medical devices. Lack of Article III standing and federal preemption clearly foreclose any such approach and call for dismissal of the entire Complaint. Even if those doctrines did not bar Harris's claims, each of the claims individually is deficient under other well-established legal principles.

Dated: September 22, 2023

Respectfully submitted,

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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

TERRY HARRIS, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

MEDTRONIC INC., MEDTRONIC USA, INC.,

Defendants.

Civil No. 0:23-cv-02273 (ECT/DLM)

WORD COUNT COMPLIANCE CERTIFICATE

The undersigned hereby certifies, pursuant to Local Rule 7.1(f) that Defendants' Memorandum of Law in Support of Motion to Dismiss contains 7,150 words, as determined through the word count feature of Microsoft Word version 2302, used to prepare the memorandum. The word processing program has been applied specifically to include all text, including headings, footnotes and quotations. The memorandum was prepared in 13-point font in accordance with the type and size limitation of Local Rule 7.1(f).

Dated: September 22, 2023

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